

JUDGE MARRERO

16 CV 7876

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

TESARO, INC.,

Plaintiff,

v.

MYRIAD GENETIC LABORATORIES, INC.,

Defendant.

Civil Action No. _____

OCT 07 2016

CASHIER'S OFFICE

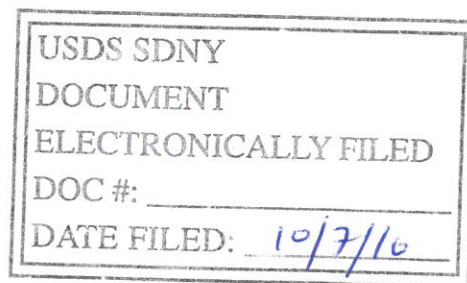
DEMAND FOR JURY TRIAL

COMPLAINT FOR INJUNCTIVE RELIEF

Plaintiff Tesaro, Inc. ("Tesaro"), by its undersigned counsel, hereby brings this Complaint against Defendant Myriad Genetic Laboratories, Inc. ("Myriad"), and states and alleges the following:

1. This is an action seeking temporary and preliminary injunctive relief, as well as other appropriate equitable relief, to enjoin Myriad from issuing a press release in violation of its express contractual obligations and the Lanham Act.

2. Myriad notified Tesaro at approximately 8:00 am ET today that it intends to issue a press release (the "Press Release") at 8:15 AM CET (2:15 AM ET) tomorrow, October 8, 2016. The draft of the Press Release provided to Tesaro purports to disclose confidential information belonging to Tesaro, including clinical data relating to Tesaro's investigational oral PARP inhibitor, niraparib. As a result, the Press Release violates a number of express provisions of a



September 30, 2014 Development Agreement between the parties (the “Development Agreement”), including paragraphs 13.1 (confidentiality), 14.2 (press releases) and 14.2 (publication of clinical data).

3. The Press Release also contains false and misleading statements in violation of the Lanham Act. Among other things, the Press Release skews study data, misrepresents clinical endpoints, and focuses on an “overall toxicity profile” without providing any information on the niraparib safety profile. The Press Release also contains false and misleading statements quoting third parties purporting to describe Tesaro’s drug product and related data, including some who have never seen the relevant data.

4. Because timing considerations make filing this Complaint and related TRO papers under seal impracticable, Tesaro will provide confidential copies of the Development Agreement and draft Press Release in court.

PARTIES

5. Plaintiff Tesaro, Inc. is a Delaware corporation with its principal place of business at 1000 Winter Street, Suite 3300, Waltham, MA 02451.

6. Defendant Myriad Genetic Laboratories, Inc. is a Delaware corporation with its principal place of business at 320 Wakara Way, Salt Lake City, Utah 84108.

JURISDICTION AND VENUE

7. This Court has personal jurisdiction over the parties pursuant to paragraph 17.1(b) of the Development Agreement, pursuant to which the parties consented to the jurisdiction of this court for actions arising out of the Development Agreement.

8. Subject matter jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331 (federal question), 1367, and 1332. The amount in controversy is valued at more than \$75,000.

9. Venue is proper in this Court under 28 U.S.C. § 1391, and because the Development Agreement provides that venue is proper in this Court.

NATURE OF THE CASE

10. The Development Agreement requires Myriad to “keep confidential and not to use, except for the purposes of conducting the Project ... any Confidential Information of TESARO or its affiliates, including the Clinical Data.” Development Agreement ¶ 13.1.

11. The Development Agreement also places Tesaro squarely in control over publication of its own clinical data. Among other things, it provides that “Tesaro will be responsible for and control the timing and scope of any Publication of Clinical Data or Tesaro Project Inventions.” *Id.* ¶ 14.2. In addition, the Development Agreement provides that “Myriad shall not have the right to publish, present or use the Clinical Data, the Tesaro Project Inventions or any portion thereof for any Publication without Tesaro’s prior written consent.” *Id.*

12. The Development Agreement also provides for a clear process pursuant to which Myriad must pre-clear publication of data. “At least thirty (30) calendar days prior to submission of a Publication, the publishing Party shall submit to the other Party for review any proposed Publication.” *Id.* The Development Agreement also provides a process for approving press releases. *Id.* 14.1

13. Contrary to all of these express contractual requirements, Myriad notified Tesaro this morning that it intended to issue the Press Release at 2:15 ET on Saturday, October 8, 2016. Among other things, the draft Press Release provided by Myriad: (i) discloses confidential

clinical data belonging to Tesaro, including clinical data; and (ii) violates Tesaro's contractual right to control the timing and scope of its disclosure of clinical data.

14. In addition, the draft press release contains a number of false and misleading statements regarding Tesaro's drug product and clinical data relating to same. Among other things, the Press Release skews study data, misrepresents clinical endpoints, and focuses on an "overall toxicity profile" without providing any information on the niraparib safety profile. The Press Release also contains false and misleading statements quoting third parties purporting to describe Tesaro's drug product and related data, including some who have never seen the relevant data.

15. Absent immediate injunctive relief, Myriad's conduct threatens to cause Tesaro immediate and irreparable harm in the form of reputational harm, loss of goodwill, and foregone business opportunities.

CLAIMS FOR RELIEF

Count I (Breach of Contract)

16. Tesaro realleges, reasserts, and incorporates by reference herein each of the allegations contained in the foregoing paragraphs of the Complaint as though set forth fully herein.

17. There exists between the parties a binding, enforceable contract.

18. At all times, Tesaro has materially performed all of its obligations under the contract.

19. Myriad's actions constitute a material breach of the Development Agreement. Myriad's recent actions also constitute anticipatory repudiation of the Development Agreement.

20. As a direct and proximate result of Myriad's breach, Tesaro has suffered and will suffer irreparable harm, including reputational harm, loss of goodwill, and loss of business opportunities.

**Count II
(Lanham Act)**

21. Tesaro realleges, reasserts, and incorporates by reference herein each of the allegations contained in the foregoing paragraphs of the Complaint as if set forth fully herein.

22. Myriad has threatened to make false and/or misleading statements about Tesaro's drug product in commercial advertisements and promotional materials, in violation of the Lanham Act, 15 U.S.C. § 1125. Among other things, the Press Release skews study data, misrepresents clinical endpoints, and focuses on an "overall toxicity profile" without providing any information on the niraparib safety profile. The Press Release also contains false and misleading statements quoting third parties purporting to describe Tesaro's drug product and related data, including some who have never seen the relevant data.

23. Absent immediate injunctive relief, these false and misleading statements will be distributed in interstate commerce. The advertisements contain literally false statements, as well as misleading statements and/or failures to disclose.

24. The statements are directed to potential consumers, including both physicians and patients, and unless enjoined will be disseminated to a substantial portion of the target audience.

25. The statements will deceive or are likely to deceive a substantial segment of potential customers regarding the nature and characteristics of Tesaro's drug product.

26. The statements are material, because they concern an inherent quality or characteristic of Tesaro's drug product.

27. The statements will proximately cause harm to Tesaro, under the standards set forth by the Supreme Court in *Lexmark*.

28. The false and misleading statements were contained in or amount to an advertising campaign or promotion, targeted toward physicians and patients.

29. Tesaro has been or is likely to be injured as a result of Myriad's false and misleading statements.

30. Myriad's false and misleading statements and omissions violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

31. Unless enjoined, Myriad's actions will cause irreparable harm to Tesaro, including reputational harm and loss of good will, for which there is no adequate remedy at law. Myriad therefore is entitled to an injunction under 15 U.S.C. § 1116 restraining Myriad, its agents, employees, representatives and all persons acting in concert with them from engaging in future acts of false advertising and ordering removal of all of Tesaro's false advertisements.

32. Pursuant to 15 U.S.C. § 1117, Tesaro is entitled to recover the costs of this action.

33. Upon information and belief, Myriad knew that its commercial advertisements and promotional materials were false and/or misleading, or Myriad acted with reckless disregard to the truth of such statements. Myriad's conduct is willful, deliberate, intentional and in bad faith, and undertaken with the intention of causing confusion, mistake or deception. As a result, this is an exceptional case entitling Tesaro to recover additional damages and reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for the following relief:

- A. Temporary and preliminary injunctive relief enjoining Defendant from issuing the Press Release and/or otherwise violating the Development Agreement and/or making false and misleading statements under the Lanham Act;
- B. An order awarding plaintiff's costs, expenses and attorneys' fees; and/or
- C. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff respectfully demands a trial by jury of any and all issues triable of right before a jury.

Dated: October 7, 2016

HOGAN LOVELLS US LLP

By: _____

William Regan

875 Third Avenue
New York, New York 10022
Telephone: (212) 918-3000
Facsimile: (212) 918-3100

Attorney for Plaintiff